



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-19-BPL; Docket No. CDC-2019-0079]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population. CDC will conduct a study of 50 people highly exposed to cyanobacterial harmful algal blooms (CyanoHABs) to assess exposure to CyanoHAB aerosols and determine if exposure is associated with health symptoms and/or outcomes.

**DATES:** CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0079 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

## Proposed Project

Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population - New - National Center for Environmental Health, Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

CDC's National Center for Environmental Health (NCEH) has conducted two studies to investigate the associations between exposure to cyanoHAB toxins and health outcomes. In a 2006 study of recreational microcystin (MC) exposure at a small lake, CDC recruited 104 study participants from lake visitors planning recreational activities, such as boating, that would generate aerosols. During data collection for that study, MC concentrations within the bloom lake water were very low (<2-5 mg/L). Study participants' plasma MC concentrations were all below the limit of detection (0.147 mg/L) for the enzyme-linked immunosorbent assay (ELISA).

In 2007 CDC/NCEH conducted a study of recreational MC exposure among 81 children and adults planning recreational activities on either of three California reservoirs—two with

significant, ongoing blooms of toxin-producing cyanobacteria, including *Microcystis aeruginosa* and one without a toxin-producing algal bloom. Our findings indicated that recreational activities in water bodies that experience toxin-producing cyanobacterial blooms generate aerosolized cyanotoxins, making inhalation a potential route of exposure.

It is likely that healthy people will not have adverse acute effects from periodic exposures to MC in aerosols generated by water based recreational activities in lakes with patches of toxin producing blooms. However, microcystins are potent liver toxins, and exposure may lead to more long-term effects. Other potent cyanotoxins, such as anatoxin-a or cylindrospermopsin may be incorporated into aerosols and inhaled and deposited in the body, presenting other, potentially synergistic, health risks. In addition, it is possible that swimming and other water-based activities that result in swallowing water present a higher risk for adverse health effects from ingesting cyanobacterial cells and extracellular toxins in the water.

CyanoHABs may present additional health risks as they senesce, or die off. Previous work done in Wisconsin demonstrated low but measurable concentrations of hydrogen sulfide and methane, both respiratory irritants, in the air near dense and decomposing cyanobacterial blooms.

The subpopulation to be studied comprises adults at least 18 years of age, who have extensive occupational exposure to CyanoHABs on Lake Okeechobee, Florida and connecting rivers. The study will be conducted on Lake Okeechobee, Florida, U.S.A., which has a history of prolonged CyanoHAB events.

CDC will notify potentially interested participants using posted flyers with a phone number to call. CDC will recruit participants using a phone-based screening survey to determine eligibility. Eligible study participants will complete three appointments (at the beginning of the study to provide baseline data and in the middle and end of the study period). During the interviews, participants will complete a survey, do a pulmonary function test, provide urine and nasal swabs for analysis of cyanotoxins, and provide a blood specimen for analysis of liver enzyme levels and creatinine. Before (pre-exposure) and after (post-exposure) each of 12 boat trips, study participants will complete the survey and provide urine and nasal swab specimens. Study participants will donate one fish from each trip to be analyzed for cyanobacterial toxins and the GPS Exchange Format (GPX) file of the boat's travels.

Results from surveys, blood and urine specimens, nasal swabs, pulmonary function test results, air, and fish samples will be analyzed using univariate methods to summarize the data. CDC staff will compare the following information to determine if

there are correlations: 1) individual's pre-exposure results with post-exposure results, and 2) biomonitoring results with cyanotoxin levels in air and water. CDC staff will assess environmental and biomonitoring over time, and overlay satellite photos provided by NOAA with GPX tracking files from the boats to further assess exposure. The total annualized burden to respondents is 784 hours.

#### Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Interested community members	Screening survey	70	1	15/60	6
Eligible study participants	Survey	50	27	15/60	113
Eligible study participants	Blood Specimen Results	50	3	15/60	13
Eligible study participants	Nasal Swab Results	50	27	10/60	75
Eligible study participants	Lung Function Test Results	50	27	45/60	338
Eligible study participants	Urine Specimen Results	50	27	10/60	75
Eligible study participants	GPX File of Trip	50	12	15/60	50
Eligible study participants	Record of fish for Analysis by EPA	50	12	30/60	102

Total		784
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**Jeffrey M. Zirger,**

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